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Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet	1	of	7	Attorney Docket Number	20342/1202653-US3
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Complete if Known

Application Number	10/758,417-Conf. #5644
Filing Date	January 16, 2004
First Named Inventor	Beth A. Burnside
Art Unit	1617
Examiner Name	S. Wang
Attorney Docket Number	20342/1202653-US3

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
/KC/	AA	US-6,913,768	07-05-2005	Couch et al.	
/KC/	AB	US-6,764,696	07-20-2004	Pather et al.	
/KC/	AC	US-6,749,867	06-15-2004	Robinson et al.	
/KC/	AD	US-6,605,300	08-12-2003	Burnside et al.	
/KC/	AE	US-6,322,819	11-27-2001	Burnside et al.	
/KC/	AF	US-5,846,568	12-08-1998	Olinger et al.	
/KC/	AG	US-5,773,031	06-30-1998	Shah et al.	
/KC/	AH	US-5,733,575	03-31-1998	Mehra, et al.	
/KC/	AI	US-5,618,559	04-08-1997	Desai, et al.	
/KC/	AJ	US-5,501,861	03-26-1996	Makino et al.	
/KC/	AK	US-5,422,121	06-06-1995	Lehmann et al.	
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/KC/	AM	US-5,202,159	04-13-1993	Chen et al.	
/KC/	AN	US-5,137,733	08-11-1992	Noda et al.	
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/KC/	AP	US-3,979,349	09-07-1976	H. Fink	
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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
/KC/	BA	EP 0 640 337	03-01-1995	Okada Minoru		
/KC/	BB	WO-WO99/03471	01-28-1999	Atul M Mehta		
/KC/	BC	WO-WO00/25752	05-11-2000	John G Devane		
/KC/	BD	AU-109,438	01-11-1940	I. Lipowski		

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Examiner's signature	/Kendra Carter/	Date Considered	04/12/2007
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/KC/	CA	Adderall XR Package Inset, Sept. (2004)	
/KC/	CB	Agyilrah GA and Banker SB; Polymers for Enteric Coating applications, Polymers for Controlled Drug Delivery (Peter J. Tarcha ed. 1991) 39-66	
/KC/	CC	American Chemical Society, Polymer Preprints, pp. 633-634, Vol. 34, No. 1, March 1993	
/KC/	CD	Ansel, et al., Rate Controlled Dosage Forms and Drug Delivery Systems, Pharmaceutical Dosage Forms and Drug Delivery Systems, 6th Ed. (1995), 213-222	
/KC/	CE	Answering Expert Report of Dr. Alexander M. Klibanov, expert for Shire Laboratories, Inc., April 25, 2005	
/KC/	CF	Answering Expert Report of Robert Langer, Sc. D. Regarding United States Patent Nos. 6,322,819 and 6,605,300, expert for Shire Laboratories Inc., dated April 25, 2005	
/KC/	CG	Barr Laboratories' Objections and Responses to Plaintiff Shire Laboratories Inc.'s Fifth Set of Interrogatories (No. 17), dated September 3, 2004	
/KC/	CH	Barr Laboratories' Amended Answer, Affirmative Defenses And Counterclaims Shire Laboratories, Inc. v. Barr Laboratories, Inc., Civil Action No. 03-CV-1219-PKC	
/KC/	CI	Barr Laboratories' Answer, Affirmative Defenses, and Counterclaims, dated September 25, 2003	
/KC/	CJ	Barr Laboratories Inc.'s Objections and Responses to Shire Laboratories Inc.'s Second Set of Interrogatories (Nos. 8-11), dated February 18, 2004	
/KC/	CK	Barr Laboratories Inc.'s Objections and Responses to Shire Laboratories Inc.'s Fourth Set of Interrogatories (Nos. 15-16), dated July 9, 2004	
/KC/	CL	Barr Laboratories' Memorandum in Support of Its Motion to Amend Its Pleadings and exhibits thereto, dated September 10, 2004	
/KC/	CM	Barr Laboratories' Memorandum in Support of Its Motion to Compel Production, dated September 13, 2004	
/KC/	CN	Barr Laboratories' Supplemental Objections and Responses to Plaintiff Shire Laboratories Inc.'s Third Set of Interrogatories (Nos. 12-14)(Redacted), dated August 27, 2004	
/KC/	CO	Barr Laboratories, Inc.'s '300 Notification Pursuant to §505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. § 314.95)	
/KC/	CP	Barr Laboratories, Inc.'s '819 Notification Pursuant to §505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(j)(2)(B)(ii) and 21 C.F.R. § 314.95)	
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			Examiner Name	S. Wang	
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/KC/	CZ	Chang et al., Preparation and Evaluation of Shellac Pseudolatex as an Aqueous Enteric Coating Systems for Pellets, International Journal of Pharmaceuticals, 60 (1990) 171-173	
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/KC/	CB1	Civil Docket For Case #: 1:03-cv-01164-GMS Shire Laboratories, Inc. v. Impax Laboratories, Inc., Civil Action No. 03-CV-01164-GMS	
/KC/	CC1	Civil Docket For Case #: 1:03-cv-01219-PKC-DFE Shire Laboratories, Inc. v. Barr Laboratories, Inc., Civil Action No. 03-CV-1219-PKC	
/KC/	CD1	Civil Docket For Case #: 1:03-cv-06632-VM-DFE Shire Laboratories, Inc. v. Barr Laboratories, Inc., Civil Action No. 03-CV-6632-PKC	
/KC/	CE1	Civil Docket For Case #: 1:05-cv-00020-GMS Shire Laboratories, Inc. v. Impax Laboratories, Inc., Civil Action No. 05-20-GMS	
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/KC/	CH1	Daynes, Treatment of Nocturnal Enuresis with Enteric-Coated Amphetamine, The Practitioner, No. 1037, Vol. 173, November 1954	
/KC/	CI1	Deposition of Transcript of Beth Burnside, dated 2/2/05	
/KC/	CJ1	Deposition of Transcript of Beth Burnside, dated 2/3/05	
/KC/	CK1	Deposition of Transcript of Charlotte M. McGuiness, dated 8/6/04	
/KC/	CL1	Deposition of Transcript of Donald John Treacy, Jr., dated 8/31/04	
/KC/	CM1	Deposition of Transcript of Edward Rudnic, dated 7/28/04	
/KC/	CN1	Deposition of Transcript of James J. Harrington, dated July 27, 2005	
/KC/	CO1	Deposition of Transcript of Kimberly Fiske, dated 9/17/04	
/KC/	CP1	Deposition of Transcript of Richard Rong-Kun Chang, dated 1/20/05	
/KC/	CQ1	Deposition of Transcript of Richard A. Couch, dated 9/14/04	
/KC/	CR1	Deposition of Transcript of Robert Schaffer, dated August 17, 2005	
/KC/	CS1	Deposition of Transcript of Xiaodi Guo, dated 1/24/05	
/KC/	CT1	Deposition of Transcript of Xiaodi Guo, dated 7/26/04	
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/KC/	CY1	Expert Report of the Honorable Gerald J. Mossinghoff, expert for Barr Laboratories, Inc. and exhibits thereto, March 16, 2005	
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/KC/	CB2	Garnett et al., Pharmacokinetic Evaluation of Twice-Daily Extended-Release	
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		Examiner Name	S. Wang		
Sheet	4	of	7	Attorney Docket Number	20342/1202653-US3

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/KC/	CQ2	Impax Laboratories Answer And Affirmative Defenses <i>Shire Laboratories, Inc. v. Impax Laboratories, Inc.</i> , Civil Action No. 03-CV-01164-GMS	
/KC/	CR2	Impax Laboratories, Inc.'s First Supplemental Responses to Shire Laboratories Inc.'s First Set of Interrogatories (Nos. 11-12) dated 3/28/05	
/KC/	CS2	Impax Laboratories, Inc.'s Memorandum in Support of the Motion to Amend Its Answer dated 2/25/05 and exhibits thereto	
/KC/	CT2	Impax Laboratories, Inc.'s Reply Memorandum in Support of the Motion to Amend Its Answer dated 3/18/05 and exhibits thereto	
/KC/	CU2	Impax Laboratories, Inc.'s First Amended Answer and Affirmative Defenses, dated May 2, 2005	
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/KC/	CN3	Office Action in U.S. Patent Application Serial No. 11/091,010, mailed February 3, 2006	
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/KC/	CP3	Response to Office Action filed July 18, 2006 in U.S. Patent Application No. 11/091,010	
/KC/	CQ3	Office Action in U.S. Patent Application Serial No. 11/091,010, mailed October 10, 2006	
/KC/	CR3	Office Action mailed March 2, 2005 in European Patent Application No. 99 970594.0-2123	
/KC/	CS3	Opening Expert Report of Dr. Michael Mayersohn, expert for Impax Laboratories Inc. and exhibits thereto, March 12, 2005	
/KC/	CT3	Opening Expert Report of Dr. Walter Chambliss, expert for Impax Laboratories, Inc. and exhibits thereto, March 15, 2005	
/KC/	CU3	Order Construing The Terms Of U.S. Patent Nos. 6,322,819 And 6,605,300 <i>Shire Laboratories, Inc. v. Impax Laboratories, Inc.</i> , Civil Action No. 03-CV-01164-GMS	
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/KC/	CH4	Remington's Pharmaceutical Sciences, Fifteenth Edition (1975) 1624-1625	
/KC/	CI4	Remington's Pharmaceutical Sciences, RPS XIV, 1700-1714	
/KC/	CJ4	Reply to Barr Laboratories Inc.'s Amended Answer, Affirmative Defenses And Counterclaims <i>Shire Laboratories, Inc. v. Barr Laboratories, Inc.</i> , Civil Action No. 03-CV-1219-PKC	
/KC/	CK4	Reply to Barr Laboratories Inc.'s Amended Answer, Affirmative Defenses And Counterclaims <i>Shire Laboratories, Inc. v. Barr Laboratories, Inc.</i> , Civil Action No. 03-CV-6632-PKC	
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/KC/	CB5	The Merck Index: Amphetamine, 13th Ed. (2001), 97, 1089	
/KC/	CC5	The United States Pharmacopeia 23, National Formulary 18 (1995) pp. 1791-1799	
/KC/	CD5	The United States Pharmacopeia 26, National Formulary 21 (2003) pp. 2157-2165	
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Examiner's signature	/Kendra Carter/	Date Considered	04/12/2007
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/758,417-Conf. #5644	
			Filing Date	January 16, 2004	
			First Named Inventor	Beth A. Burnside	
			Art Unit	1617	
			Examiner Name	S. Wang	
Sheet	7	of	7	Attorney Docket Number	20342/1202653-US3

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/KC/	CM5	Court Docket for <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated January 8, 2007	
/KC/	CN5	Complaint in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , and exhibits thereto, Case No. 2:06 -cv-00952-SD dated March 2, 2006	
/KC/	CO5	Answer and Counterclaims in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated July 24, 2006	
/KC/	CP5	Reply To Counterclaims in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated August 16, 2006	
/KC/	CQ5	Defendants' Responses to Plaintiff Shire's First Set of Interrogatories (1-12) in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated September 20, 2006	
/KC/	CR5	Defendants' Responses to Plaintiff's First Set of Request for the Production of Documents and Things (1-70) in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated October 4, 2006	
/KC/	CS5	Plaintiff's Response to Defendants' First Set of Interrogatories in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated October 11, 2006	
/KC/	CT5	Plaintiff's Response to Defendants' First Set of Production Requests in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated October 11, 2006	
/KC/	CU5	Defendants' Responses to Plaintiff's Second Set of Requests for the Production of Documents and Things (71-80) in <i>Shire Laboratories Inc. v. Teva Pharmaceutical Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated November 8, 2006	
/KC/	CV5	Defendants' Responses to Plaintiff Shire's Second Set of Interrogatories (No. 13) in <i>Shire Laboratories v. Teva Pharmaceuticals Industries Ltd.</i> , Case No. 2:06-cv-00952-SD dated November 8, 2006	
/KC/	CW5	Petition Under Section 8 and exhibits thereto, submitted to the Canadian Patent Office on December 4, 2006	
/KC/	CX5	Office Action in U.S. Patent Application Serial No. 11/091,011, mailed December 1, 2006	
/KC/	CY5	Response to Non-Final Office Action filed January 10, 2007 in U.S. Patent Application No. 11/091,011	
/KC/	CZ5	Response to Non-Final Office Action filed January 10, 2007 in U.S. Patent Application No. 11/091,010	

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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner's signature	/Kendra Carter/	Date Considered	04/12/2007
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete If Known		
			Application Number	10/758,417-Conf. #5644	
			Filing Date	January 16, 2004	
			First Named Inventor	Beth A. Burnside	
			Art Unit	1615	
			Examiner Name	S. Wang	
Sheet	1	of	1	Attorney Docket Number	20342/1202653-US3

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
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/KC/	BA	EP-0640337	03-01-1995	Ss Pharmaceutical Co		

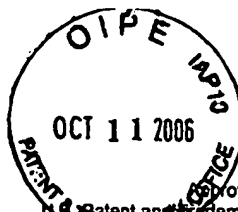
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NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/KC/	CA	European Office Action dated January 19, 2007 issued for corresponding European Patent Application No. 99970594.0.	

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Examiner Signature	/Kendra Carter/	Date Considered	04/12/2007
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				Application Number	10/758,417-Conf. #5644
				Filing Date	January 16, 2004
				First Named Inventor	Beth A. Burnside
				Art Unit	1617
				Examiner Name	S. Wang
Sheet	1	of	1	Attorney Docket Number	20342/1202653-US3

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		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				

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/KC/	NPLD1	Amendment After Final Rejection, dated April 21, 2003, filed in U.S. Patent Application No. 09/807,462 (now U.S. Patent No. 6,605,300).	

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¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Kendra Carter/	Date Considered	04/12/2007
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 4

Complete if Known

Application Number	10/758,417
Filing Date	January 16, 2004
First Named Inventor	Beth A. BURNSIDE et al.
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	Pharma-0142-C02

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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/KC/	A2	6,228,398	B1	Devane t al.	05/08/2001	
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/KC/	B2	WO	00/35450			06/22/2000		
/KC/	B3	WO	00/35426			0622/2000		
/KC/	B4	WO	99/30694			06/24/1999		
/KC/	B5	WO	97/03672			02/06/1997		
/KC/	B6	EP	0 212 747			03/04/1987		

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Signature

/Kendra Carter/

Date
Considered

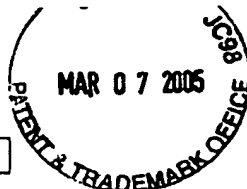
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet **2** of **4**

Complete if Known

Application Number	10/758,417
Filing Date	January 16, 2004
First Named Inventor	Beth A. BURNSIDE et al.
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	PHARMA-0142-C02

U.S. PATENT DOCUMENTS

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		Number	Kind Code ² (if known)			
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/KC/	A24	5,840,329		Bai	11/24/1998	
/KC/	A25	5,837,284	A	Mehta et al.	11/17/1998	
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/KC/	A30	5,093,200		Watanabe et al.	03/03/1992	
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/KC/	A37	5,051,262		Panoz et al.	09/24/1991	
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/KC/	A41	4,917,899		Geoghegan et al.	04/17/1990	
/KC/	A42	4,902,516		Korsatko et al.	02/20/1990	
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/KC/	A45	4,871,549		Ueda et al.	10/03/1989	
/KC/	A46	4,765,989		Wong et al.	08/23/1989	
/KC/	A47	6,322,819		Burnside et al.	11/2001	
/KC/	A48	5,837,284		Mehta et al.	11/1998	

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/KC/	B7	WO	00/23055			04/27/2000		
/KC/	B8	WO	87/00044			01/15/1987		
/KC/	B9	WO	90/09168			08/23/1990		

Examiner
Signature

/Kendra Carter/

Date
Considered

04/12/2007

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Sheet 3

of

4

Complete if Known

Application Number	10/758,417
Filing Date	January 16, 2004
First Named Inventor	Beth A. BURNSIDE et al.
Group Art Unit	1615
Examiner Name	Unassigned
Attorney Docket Number	PHARMA-0142-C02

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/KC/	C1	K. S. PATRICK et al., "Pharmacology of Methylphenidate, Amphetamine Enantiomers and Pemoline in Attention-Deficit..." HUMAN PSYCHOPHARMACOLOGY, Vol. 12, pp. 527-546, 1997.	
/KC/	C2	Lisa H. BRAUER et al., "Acute Tolerance to Subjective but Not Cardiovascular Effects of d-Amphetamine in Normal, Healthy Men," JOURNAL OF CLINICAL PSYCHOPHARMACOLOGY, Vol. 16, No. 1, pp. 72-76, 1996.	
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/KC/	C5	S.B. SPARBER et al., "Amphetamine Cumulation and Tolerance Development: Concurrent and Opposing Phenomena," PHARMACOLOGY BIOCHEMISTRY & BEHAVIOR, Vol. 20, pp. 415-424, 1984.	
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/KC/	C11	Barr Laboratories' Answer, Affirmative Defenses and Counterclaim in Case No. 03-CV-1219(VM)(DFE) (S.D.N.Y.)	

Examiner
Signature

/Kendra Carter/

Date
Considered

04/12/2007

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		First Named Inventor	Beth A. BURNSIDE et al.
		Group Art Unit	1615
		Examiner Name	Unassigned
		Attorney Docket Number	PHARMA-0142-C02
Sheet	4	of	4

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
/KC/	C12	WALIA et al., Preliminary Evaluation of an Aqueous Wax, Emulsion for Controlled-Release Coating, Pharm. Dev. Tech., vol. 3, no. 1, pp. 103-113 (1998).	
/KC/	C13	BANKER et al., "Modern Pharmaceuticals, eds., Marcel Dekker, Inc., New York, pg. 350 (1996)	
/KC/	C14	Gazzaniga et al., "Time-Dependent oral Delivery Systems for Colon Targeting," S.T.P. Pharma Sciences 5(1):83-88 (1995).	
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/KC/	C23	Dexedrine, Spansule Capsules, Package Insert, Physicians' Desk Reference 1997.	
/KC/	C24	ADDERALL, Package Insert, May 1996, Physicians' Desk Reference 1997.	
/KC/	C25	Barr's Paragraph IV Certification against Parent U.S. Patent 6,322,819, of January 14, 2003	

Examiner Signature	/Kendra Carter/	Date Considered	04/12/2007
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